UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION NO. 01-12257-PBS
THIS DOCUMENT RELATES TO:	SUBCATEGORY CASE NO. 03-10643-PBS
THE CITY OF NEW YORK, et al., Plaintiff, v. ABBOTT LABORATORIES, et al., Defendant.	

MEMORANDUM AND ORDER

December 4, 2009

Saris, U.S.D.J.

I. INTRODUCTION

New York City and forty-two New York counties have brought suit against numerous pharmaceutical manufacturers and subsidiaries alleging Medicaid fraud in violation of the federal Best Prices statute, 42 U.S.C. § 1369r, and state law including alleged violations of New York's consumer protection statute, N.Y. Gen. Bus. Law § 349.[1] Defendant SmithKline Beecham

[1] The statute provides monetary relief for any person injured by reason of "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state."

Corporation, d/b/a GlaxoSmithKline ("GSK") has moved for partial summary judgment on the ground that most of its brand name drugs meet the so-called List Price Test set forth in In re Pharmaceutical Industry Average Wholesale Price Litigation, 491 F. Supp. 2d 20, 104-06 (D. Mass. 2007), aff'd, 582 F.3d 156 (1st Cir. 2009).[2] GSK argues that 208 of the 262 drugs at issue in this case pass the List Price Test. Plaintiffs disagree with GSK as to the appropriate method for determining whether a particular drug passes the test, disputing GSK's exclusion of rebates paid to payors in its calculation of each drug's actual acquisition cost.

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[2] The background of this case has already been fully set out by the Court. See City of New York v. Abbott Labs., No. 01-cv-2257, 2007 WL 1051642 (D. Mass. Apr. 2, 2007). The Court assumes familiarity with that decision. The drug pricing schemes at issue in this case are also discussed in the Court's previous AWP-related decisions. See In re Pharm. Indus. Average Wholesale Price Litig., 263 F. Supp. 2d 172 (D. Mass. 2003); In re Pharm. Indus. Average Wholesale Price Litig., 307 F. Supp. 2d 196 (D. Mass. 2004); In re Pharm. Indus. Average Wholesale Price Litig., 321 F. Supp. 2d 187 (D. Mass. 2004); In re Pharm. Indus. Average Wholesale Price Litig., 339 F. Supp. 2d 165 (D. Mass. 2004); In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61 (D. Mass. 2005); In re Pharm. Indus. Average Wholesale Price Litig., 460 F. Supp. 2d 277 (D. Mass. 2006); In re Pharm. Indus. Average Wholesale Price Litig., 478 F. Supp. 2d 164 (D. Mass. 2007); In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 12 (D. Mass. 2007); In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20 (D. Mass. 2007); In re Pharm. Indus. Average Wholesale Price Litig., 538 F. Supp. 2d 367 (D. Mass. 2008); In re Pharm. Indus. Average Wholesale Price Litig., 252 F.R.D. 83 (D. Mass. 2008); see also Massachusetts v. Mylan Labs., Inc., 357 F. Supp. 2d 314 (D. Mass. 2005); Massachusetts v. Mylan Labs., Inc., 608 F. Supp. 2d 127 (D. Mass. 2008).

After briefing and a hearing, Defendant's motion is **DENIED**. While Defendant has the better argument regarding methodology, this fact is not necessarily determinative.

II. DISCUSSION

A. Standard of Review

"Summary judgment is appropriate when 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.'" Barbour v. Dynamics Research Corp., 63 F.3d 32, 36-37 (1st Cir. 1995) (quoting Fed. R. Civ. P. 56(c)). "To succeed [in a motion for summary judgment], the moving party must show that there is an absence of evidence to support the nonmoving party's position." Rogers v. Fair, 902 F.2d 140, 143 (1st Cir. 1990); see also Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986).

"Once the moving party has properly supported its motion for summary judgment, the burden shifts to the non-moving party, who 'may not rest on mere allegations or denials of his pleading, but must set forth specific facts showing there is a genuine issue for trial.'" Barbour, 63 F.3d at 37 (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986)). "There must be 'sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely

colorable or is not significantly probative, summary judgment may be granted.'" Rogers, 902 F.2d at 143 (quoting Anderson, 477 U.S. at 249-50). The Court must "view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." Barbour, 63 F.3d at 36.

B. The List Price Test

As background, in the Track One trial where the plaintiffs were challenging the Average Wholesale Prices ("AWPs") of the brand name drugs of four defendant companies, the "[p]laintiffs' core claim [was] that the published AWPs for [the] defendants' drugs [were] fictitious because they [did] not reflect the true average sales price" of the drugs. In re Pharm. Indus. Average Wholesale Price Litig., 491 F.Supp 2d at 30. Unlike the drugs at issue here, the drugs at issue at that trial were, for the most part, administered by doctors, and sold principally to physicians, rather than "intermediaries" like wholesalers. Id. at 29, 71. "Because AWP is the predominant benchmark for reimbursement by the government and third-party payors, plaintiffs contend[ed] that manufacturers grossly inflate[d] each drug's AWP to create a 'spread' between the doctor's real acquisition cost and the fictitious published AWP, and that drug manufacturers then 'market[ed] the spread' in order to obtain market share over a competitor's drug." Id. at 30. "The key question in [the] litigation [was] whether causing the

publication of an AWP that greatly exceed[ed] the average sales price charged to a doctor or pharmacist for certain drugs covered by Medicare Part B [was] an unfair and deceptive practice under [Mass. Gen. Laws] Chapter 93A." Id. at 94.

To answer the question, the Court applied a three-factor analysis. The first and "most important inquiry asks: were there egregious [AWP] spreads above the 30% yardstick expected in the industry? In particular, I focus on the extent and duration of the spreads to evaluate egregiousness." Id. at 101-02.

The List Price Test figured in a multi-part analysis of the second factor,

> the company's history of creating the [AWP] spread. Did the manufacturer actually increase the AWP and/or list price, as opposed to just increasing the spread through discounts and rebates? Creating the spread by increasing the AWP comes at no cost to the pharmaceutical company and places the full financial burden of the spread on the payor and patient. This approach to expanding the spread is strong evidence of unethical conduct. *Also relevant to this analysis is the legitimacy of the list price from which the markup is derived: Is it a real list price at which substantial sales were made or an unfair and deceptive price used to jack up the AWP?* Finally, evidence that an AWP increase was intended to thwart Congress's change in reimbursement rates will constitute evidence of unethical behavior.

Id. at 102 (emphasis added).

At trial, Bristol-Meyers Squibb (BMS) argued that their Wholesale List Price (WLP) was a legitimate list price because a significant proportion of its sales were made at that price. Id. at 104-05. BMS only reported a WLP to the drug-industry

publications, and the publications applied the formulaic mark-up of 20 to 25 percent to derive the AWP. BMS relied on the FTC's Guides Against Deceptive Pricing, which provide that a list price "will not be deemed fictitious if it is the price at which substantial (that is, not isolated or insignificant) sales are made." Id. at 105 (quoting 16 C.F.R. § 233.3(d)). After a review of the case law, the Court held that "if more than 50 percent of all sales were made at or about the list price, the list price will not be deemed fictitious." Id.

The final factor in the three-factor analysis was whether "the defendant engage[d] in a proactive scheme to market the [AWP] spread to doctors by encouraging them to purchase drugs because of their profitability rather than their therapeutic qualities." Id. at 102.

The Court added that "[t]he weight given to each of these factors depends on the particular circumstances of each manufacturer and each drug for each year; no single factor is necessarily determinative, but the size and duration of a mega-spread is the most significant factor." Id.

GSK argues that under the List Price Test, it automatically has no liability if more than 50% of a drug's sales each year were made at transaction prices that were within 5% of the manufacturer's reported Wholesale Acquisition Cost ("WAC") for that drug. GSK overstates the role of the test. The List Price

Test is merely a sub-part of one factor in a three-factor analysis: the company's history of creating the spread. Further, the factor as a whole is not only not "determinative," but it is not even "the most significant factor."

GSK argues that none of this matters because the Court found no liability for the four drugs that satisfied the List Price Test during the Track One trial, even where the drugs had AWP spreads of over 30%. See id. at 106-08. GSK's argument is faulty. Although the Court found no liability for the drugs, it did so only after considering all of the relevant elements affecting the three-factor analysis. As a general matter, where the Court found no liability, it did so where the spreads did not exceed 30%, where the spreads exceeded 30% only slightly, or where "the spreads were not consistently above 30%." Id. at 106. While success under the List Price Test does aid GSK's position, satisfaction of the test is not determinative.

As a final explanatory note, the Court, in explaining AWP, noted that AWP was "derived from the markup charged by wholesalers over their actual acquisition cost, sometimes called the 'Wholesale Acquisition Cost' or 'WAC.'" Id. at 33. That is, WAC is meant to represent the actual acquisition cost of wholesalers.[3] As the Court explained in a related case when

[3] The parties seem to agree that the term "wholesalers" also includes other drug distributors.

construing WAC as a regulatory term, "WAC means 'the price that wholesalers actually paid to acquire the drug.'" Mylan, 608 F. Supp. 2d at 144. "It does not mean a list price; it means the amount that goods actually cost." Id. at 143. As such, in cases where the relevant statute uses WAC to determine reimbursement, a WAC that deviates from the price that wholesalers actually paid to acquire a drug is false.

C. Percentage of Sales at or near List Price

Initially, the parties disagreed about how to apply the List Price Test, advocating different methodologies for determining what percentage of a drug's sales were made at prices within 5% of the reported WAC. As background, GSK sells a quantity of a drug to a wholesaler, charging it something close to its published WAC. The wholesaler then proceeds to sell the drugs to providers. Approximately 84% of the drugs are sold with no further involvement from GSK. Approximately 16% of the drugs are sold to providers with whom GSK has a discount arrangement. In that case, the wholesaler sells the drug to the provider at the price determined by GSK, typically much less than GSK's reported WAC. GSK then pays the wholesaler a "chargeback" to make up the difference.

The parties initially disagreed about how to deal with these chargeback sales. GSK argues that each unit sold to a provider that has a chargeback agreement must be viewed as a separate

sale, apart from other sales. Each unit sold with a chargeback agreement constitutes a sale that fails the List Price Test, and each unit sold without a chargeback constitutes a sale that passes the test. To support its view, GSK argues that this was the method used in the Track One trial. But the plaintiffs there never challenged BMS' expert's method for calculating the percentage of sales made at BMS' WLP, and the Court did not discuss the subject, merely using the numbers that were provided to it without objection.

In its opening round of briefs, Plaintiffs had argued that all of the units in a sale to a wholesaler must be viewed together. The wholesaler's initial payment for all of the units in the sale is reduced by the chargebacks associated with the units, and then divided by the number of units in the sale to calculate the actual price of the drug to the wholesaler for each sale. For each sale to the wholesaler, the units, be they associated with a chargeback or not, either all fail or all pass the List Price Test.

While the debate is an interesting one, in their supplemental briefing Plaintiffs appear to have yielded to GSK's view and utilized its methodology to recalculate their figures. As the parties now appear to agree on the issue, the Court need not decide it.

D. Rebates to Payors

GSK and the Plaintiffs agree that the discounts and rebates that GSK pays to drug purchasers (e.g., wholesalers, retail pharmacies and mail order pharmacies) should be included in calculating the actual acquisition cost of the drug to the wholesaler, but they disagree about whether rebates given to entities that reimburse providers for drugs (e.g., third party payors (TPPs), like insurance companies and employee benefit plans, and pharmacy benefit managers (PBMs) that are hired by TPPs to handle reimbursements to pharmacies on behalf of TPPs) should be included. (See GSK's Supplemental Br. Ex. A (Berndt Aff.) ¶ 4.)

Plaintiffs argue that the rebates paid to entities that reimburse providers for drugs should be included in these calculations, while GSK argues they should not. These rebates are generally paid by manufacturers in exchange for placing the manufacturer's drugs on a formulary or to incentivize increased utilization of its drugs. (See id. Ex. A ¶¶ 14, 25.)

In Plaintiffs' view, rebates paid by manufacturers to payors that reimburse for drugs should be treated the same as rebates to wholesalers and providers because they are made on the basis of sales. GSK argues that rebates to payors should be treated differently because rebates paid to payors have no impact on the net cost to wholesalers. (See id. Ex. A ¶ 28.) GSK has the better argument because the relevant consideration, when

analyzing WAC, is the acquisition cost of the drug to the wholesaler. As the List Price Test was intended to analyze the true acquisition cost of wholesalers, unrelated rebates paid to entities like TPPs that do not affect that cost should not be included in the analysis.

ORDER

Defendant's motion for partial summary judgment [Docket No. 5706] is **DENIED**.

/s/ Patti B. Saris
PATTI B. SARIS
United States District Judge